K041089

AUG 3 1 2004

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, IN 46581

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: OSS Bone Graft System and OSS RapidSet Bone Graft System

Common Name: Bone Graft Substitute

Classification Name: Resorbable calcium salt bone void filler device (21 CFR 888.3045)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: The current product is identical to the material previously cleared through 510(k)s K990290, K012569 and K023718 for craniofacial applications and K003494 for dental applications.

Products cleared for orthopedic applications include: α-BSM® Bone Substitute Material (K011048), Norian® SRS® Bone Void Filler (K011897) and Pro Osteon® 500R Resorbable Bone Graft Substitute (K990131).

Device Description: OSS Bone Graft System and OSS RapidSet Bone Graft System are packaged as separate, pre-measured powder and liquid components. The two components are to be mixed intraoperatively to produce a homogenous paste that can be applied to bone gaps or defects.

The powder component is a mixture of a ceramic calcium phosphate powder and sodium citrate dihydrate. The liquid component is a solution comprised of anhydrous citric acid ($C_6H_8O_7$) and distilled water (H_2O). When mixed, the powder and liquid combine to form a homogenous paste.

Intended Use: The OSS Bone Graft System and the OSS RapidSet Bone Graft System are indicated for filling bony voids of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from disease or traumatic injury to the bone. The device is intended for bone voids or gaps that are not intrinsic to the structural integrity of the bony structure.

Summary of Technologies: The materials, design and processing OSS Bone Graft System and OSS RapidSet Bone Graft System are similar or identical to the predicate products.

Non-Clinical Testing: Non-clinical testing provided included elemental analysis, a determination of set time, X-ray diffraction analysis, determination of surface pH, and exothermic temperature.

Clinical Testing: None provided

Mimix is a trademark of Walter Lorenz Surgical, a Biomet Company
Tyvek is a trademark of trademark of E.I. duPont de Nemours and Company
α-BSM is a trademark of DePuy
Pro Osteon is a trademark of Interpore Cross International
Norian and SRS are trademarks of Synthes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2004

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corporation
P.O Box 587
Warsaw, Indiana 46581-0587

Re: K041089
OSS Bone Graft System and OSS RapidSet Bone Graft System
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: July 19, 2004
Received: July 20, 2004

Dear Ms. Sandborn Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K041089

Device Name: OSS Bone Graft System and OSS RapidSet Bone Graft System

Indications For Use:

The OSS Bone Graft System and the OSS RapidSet Bone Graft System are indicated for filling bony voids of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from disease or traumatic injury to the bone. The device is intended for bone voids or gaps that are not intrinsic to the structural integrity of the bony structure.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041089